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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/606,208  | 06/26/2003  | Barton D. Gaskins    | 067949-5025         | 4366             |
| 9629 7590 07/22/2009<br>MORGAN LEWIS & BOCKIUS LLP<br>1111 PENNSYLVANIA AVENUE NW<br>WASHINGTON, DC 20004 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| YANG, ANDREW  |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 3775  |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/606,208

**Applicant(s)**

GASKINS ET AL.

**Examiner**

ANDREW YANG

**Art Unit**

3775

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 94-102 and 111-130 is/are pending in the application.
- 4a) Of the above claim(s) 94-97 and 111 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 98-102 and 112-124 is/are rejected.
- 7) ☒ Claim(s) 125-130 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to Applicants' amendment filed on 4/1/2009.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 98-102, 106, 107, 112, 113, 118-121, and 124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stayton et al. (U.S. Patent No. 3856219) in view of Meredith (U.S. Patent No. 6755365).

Stayton et al. discloses a substrate cutting device 10 having a cutter 18 a clamping mechanism 16 and a slide mechanism 30 coupled to the cutter 18. The slide mechanism 30 reciprocates parallel to base 10 (column 2, lines 6-10) and perpendicular to the clamp mechanism 16 and is thus considered capable of sliding parallel to the length wise grain of the substrate depending on the orientation of the substrate when placed into the bone supply channel 14. The slide mechanism 30 is pneumatically operated (column 1, lines 56-60). It is considered that it is obvious to have a sensor/gauge with the pneumatic device since pressure in such devices needs to be regulated. The clamp is manually actuated. A controller, such as the operator controls both the clamp and the slide mechanism and it is considered that the controller is capable of varying the speed of the cutter and the force of the clamp. The blade section

28 of the cutter has teeth and have at least one predetermined cutting angle (Figure 4). In use a cadaver bone is placed into bone channel 14 and clamped with clamp mechanism 16 (column 1, lines 45-46). Cadaver bone is considered to be implant bone derived from a human source. Stayton et al. fails to disclose the second clamping mechanism controlled by a pneumatic actuator. Meredith teaches a bone mill device 10 having a cutting element 17 located at a distal end of a bone chute 60. The guide 60 has a clamping mechanism 66 with a contacting plate 68. The clamp mechanism is pneumatically powered to deliver the bone 22 at a consistent pressure and speed (column 6, lines 49-54). Consistent speed and pressure leads to little or no heat produced during the cutting process which allows for the preservation of morphogenetic proteins, allowing the bone to retain its osteoinductivity (column 6, lines 40-46). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Stayton et al. with the clamping mechanism actuated by a pneumatic means in view of Meredith in order to provide consistent pressure and speed to the bone so as to eliminate heat and preserve the osteoinductivity of the bone.

With regard to claim 106, With regard to claims 2 and 3, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Stayton et al. as modified by Meredith with the clamp actuation unit to apply a force of 150-250 lbs, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With regard to claim 107, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Stayton et al. as modified by Meredith with the clamp actuation unit to apply a force of 200 lbs, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 114, 116, 117, 122, and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stayton et al. (U.S. Patent No. 3856219) in view of Meredith (U.S. Patent No. 6755365) and further in view of Morris et al. (U.S. Publication No. 2006/0024656).

Stayton et al. and Meredith disclose the claimed method except for plasticizing, freezing, or, combing the substrate with glycerol prior to cutting. Morris et al. teaches a method of making bone particles where the bone is frozen (Paragraph 47), plasticized (Paragraph 50), and combined with glycerol prior to cutting (Paragraph 49). These steps result in a greater yield of particles for the available bone compared with that provided by previous methods (Paragraph 9). It would have been obvious to one skilled in the art at the time the invention was made to freeze, plasticize, or combing with glycerol prior to cutting the substrate of Stayton et al. as modified by Meredith in view of Morris et al. to provide a greater yield of particles from the available bone than compared to previous methods.

Claim 115 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stayton et al. (U.S. Patent No. 3856219) in view of Meredith (U.S. Patent No. 6755365) and further in view Schmitz (U.S. Patent No. 4637931).

Stayton et al. and Meredith disclose the claimed invention except for freeze drying the substrate. Schmitz teaches that freeze drying cortical bone has been shown to elicit little or no cell-mediated response and is the least antigenic of other bone allografts (column 3, lines 31-37). It would have been obvious to one skilled in the art at the time the invention was made to freeze dry the substrate of Stayton et al. and Meredith in view of Schmitz in order to produce an allograft that is antigenic.

***Allowable Subject Matter***

Claims 125-130 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

In response to Applicants' argument that Stayton fails to disclose a cutter containing a blade section for producing fibers, the Examiner respectfully disagrees. The device of Stayton is a mill, which is generally used for crushing/grinding a solid into smaller pieces. Bone is an inherently fibrous structure, thus crushing/grinding bone in a mill will produce smaller pieces of the fibrous structure, and thus producing bone fibers. Furthermore, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW YANG whose telephone number is (571)272-3472. The examiner can normally be reached on IFP.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew Yang/  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
Supervisory Patent Examiner, Art  
Unit 3775